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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,354	11/07/2001	Julio C. Spinelli	279.373US1	4381

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EXAMINER
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GREENE, DANA D

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/008,354	<b>Applicant(s)</b> SPINELLI ET AL.	
	<b>Examiner</b> Dana D. Greene	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/25/05 1/5/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 26 is objected to because of the following informality: line 2, "interface is for communicating" should read "interface is configured for communicating." Appropriate correction is required.

### ***Claim Rejections – 35 U.S.C. §102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. To be an "anticipation" rejection under 35 U.S.C. § 102, the reference must teach every element and recitation of the Applicants' claims. Rejections under 35 U.S.C. § 102 are proper only when the claimed subject matter is

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identically disclosed or described in the prior art. Thus, the reference must clearly and unequivocally disclose every element and recitation of the claimed invention.

4. A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently in a single prior art reference.

Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Here, independent claims 1, 15, 25, and 35 stand rejected under 35 U.S.C. §102(e) as being anticipated by Goedeke et al. (U.S. Patent No. 6,687,547 B2, hereinafter "Goedeke"). Goedeke is considered to disclose:

A control mechanism for controlling one or more operations of the IMD, which may include the provision of one, or more desired therapies and/or monitoring one or more physiologic parameters within the patient, coupled to a mechanism for delivering the desired therapies and/or sensing the physiologic parameters to be monitored (see col. 4, ln. 10-17, Goedeke). Also, Goedeke teaches prescription of the initiation and content of the session to measure physiologic parameters and provide the real-time patient data or an indication that the parameters are acceptable or not (see col. 7, ln. 62-65. Goedeke). Therefore, the elements as set forth in claims 1, 15, and 35 are found in this single prior art reference of Goedeke.

Claims 10-14, 25, 30-34, 36-39, and 46 stand rejected under 35 U.S.C. §102(e) as being anticipated by Goedeke. Goedeke discloses the concept that a wide variety of IMDs are commercially released or proposed for clinical

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implantation and are programmable in a variety of operating modes (see col. 1, In. 20-23, Goedeke). In this connection, the EMD is typically characterized as a full function or limited function programmer (see col. 1, In. 44-45, Goedeke).

Further, patients are sometimes provided with limited function programmers that typically have a limited range of programming functions and are intended for use by the patient to downlink a command to the IMD to deliver a therapy or change a therapy and/or to store physiologic data when the patient experience particular symptoms (see col.1, In. 50-55, Goedeke).

Referring to claims 25 and 30-34, Goedeke discloses a microprocessor coupled through control lines and data buses with a DTMF generator and RF programmer incorporated into a single housing (see col. 7, In. 15-18, Goedeke). This feature combined with the control mechanism coupled to a mechanism for delivering the desired therapies and/or sensing the physiologic parameters to be monitored (see col. 4, In. 10-17, Goedeke) and the fact that patients are sometimes provided with limited function programmers that typically have a limited range of programming functions and are intended for use by the patient to downlink a command to the IMD to deliver a therapy or change a therapy and/or to store physiologic data when the patient experience particular symptoms (see col.1, In. 50-55, Goedeke) clearly anticipates claims 25 and 30-34.

***Claim Rejections – 35 U.S.C. §103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to

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be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 2, 16, 26, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goedeke in view of Haller et al. (U.S. Patent No. 6,804,558 B2, hereinafter "Haller"). Goedeke is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the wide area network. Haller is considered to disclose the claimed wide area network which is a provided communications system comprising an integrated and efficient method for clinical information management in which various networks such as a wide area network (WANs) are coordinated with one another to transfer information to and from the IMD through the communication module (see col. 9, ln. 28-42, Haller). Haller teaches the encapsulation of patient information in packets and then the transmission of that information over a wide area network (see col. 3, ln. 10-16, Haller). It would have been obvious to one of ordinary skill in the art to combine the teachings of Goedeke with the wide area network found in Haller for the purpose of the centralized management system.

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8. Claims 3-9, 17-24, 27-29, and 41-45 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Goedeke in view of Haller. Goedeke is considered to disclose the claimed invention as discussed above, under the anticipatory rejection. One of ordinary skill in the art would find it obvious to combine the teachings of Goedeke with Haller's teaching of a remote expert computer system capable of determining on the basis of analysis whether the patient requires further attention, correction, or intervention (see col. 45, ln. 26-29, Haller). In this connection, Haller also discloses a prescription table particular to a patient that is stored in the implantable medical device, communication module, and/or remote system that may be quickly and readily read (see col. 46, ln. 40-45, Haller). It would have been obvious to one of ordinary skill in the art to combine the teachings of Goedeke with the prescription system and expert computer system found in Haller for the purpose of the centralized management system.

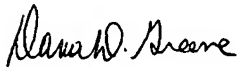
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272- 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dana D. Greene



George Manuel

Primary Examiner